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UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. CALIFORNIA STEM CELL TREATMENT CENTER, INC., et al,, Defendants.	No. 5:18-CV-01005-JGB-KKx **JOINT RULE 26(f) REPORT** Sched. Conf.: October 1, 2018 at 11:00 AM Hon. Judge Jesus G. Bernal Riverside, Courtroom 1

Plaintiff, the United States of America, and Defendants California Stem Cell Treatment Center, Inc. ("CSCTC"), Cell Surgical Network Corporation ("CSN"), Elliot B. Lander, M.D. ("Lander"), and Mark Berman, M.D. ("Berman"), by and through undersigned counsel and pursuant to Federal Rule of Civil Procedure 26(f), Local Rule 26-1, and this Court's July 18, 2018 Order Setting Scheduling Conference (D.E. 28), hereby file their joint scheduling report addressing discovery and other pretrial issues.

Pursuant to Federal Rule of Civil Procedure 26(f) and Local Rule 26-1, the following attorneys appeared telephonically to meet and confer on September 10, 2018, at 1:00 P.M. PT: undersigned counsel for the United States and Defendants' counsel Mr. Chang. Additional planning telephone conferences took place on July 2, 2018, and August 29, 2018, between aforementioned counsel. The Parties have conferred in order to present jointly this Joint 26(f) Report addressing each of the items set forth in this Court's July 18, 2018 Order Setting Scheduling Conference.

A. Statement of the Case

The United States claims that Defendants manufacture, or have caused to be manufactured, the following adipose (fat) derived products ("CSCTC products"): (1) a "stromal vascular fraction" product (the "SVF product") manufactured from a patient's adipose tissue; (2) a product that combines SVF and Vaccinia Vaccine, Live (the "SVF/Vaccinia product"); and (3) a product containing SVF that has been expanded in culture by a third party (the "expanded SVF product"), and that all such CSCTC products are intended for use in the treatment, cure, or mitigation of various diseases and conditions for which the CSCTC products are not approved. The United States further contends that Defendants' CSCTC products are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), including the FDCA's adulteration and misbranding provisions and the FDCA's Current Good Manufacturing Practice ("CGMP") regulations.

Defendants contend that they do not manufacture "products," but rather they conduct SVF procedures ("SVF procedures") which are not subject to regulation by the U.S. Food and Drug Administration ("FDA"). Defendants contend that FDA lacks jurisdiction under the FDCA and the U.S. Constitution to regulate Defendants' SVF procedures, and that the SVF procedures are exempt from regulation through the operation of either 21 C.F.R. § 1271.10(a) or the "same surgical procedure exception" of 21 C.F.R. § 1271.15(b).

The United States brings this statutory injunction proceeding pursuant to the FDCA, 21 U.S.C. § 332(a), to enjoin Defendants from (1) violating 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. §§ 352(f)(1), 352(j), and 353(b)(4), while held for sale after shipment of the drugs or one or more of their components in interstate commerce, and from (2) violating 21 U.S.C. § 331(c) by receiving misbranded drugs in interstate commerce and delivering or proffering for delivery such drugs for pay or otherwise.

The United States also seeks that FDA be authorized to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug and/or drug component to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants, as well as costs and other such relief as the Court deems just and proper, including equitable monetary relief.

B. Subject Matter Jurisdiction

In the United States' view, the basis for the Court's subject matter jurisdiction is 21 U.S.C. § 332(a), which authorizes the Court to restrain violations of § 331(c) and (k) of the FDCA. The Court also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 (federal question), 1337 (commerce), and 1345 (U.S. as plaintiff).

Defendants contest the Court's jurisdiction and have raised the lack of subject matter jurisdiction as an affirmative defense in their Answer. More specifically, and as stated above, Defendants contend that FDA and this Court lack jurisdiction under the FDCA and the U.S. Constitution to regulate Defendants' SVF procedures.

C. Legal Issues

Based on the Complaint and Defendants' Answer, the issues as presently known to the Parties are as follows:

a. Whether the Defendants' purported practices involve "drugs" within the meaning of the FDCA, 21 U.S.C. § 321(g)(1)(B), (C), and relevant regulations, 21 C.F.R. § 201.128;

b. Whether the Defendants' purported practices involve "prescription drugs" within the meaning of the FDCA, 21 U.S.C. § 353(b)(1)(A);

c. Whether the Defendants' purported practices involve "new drugs" within the meaning of the FDCA, 21 U.S.C. § 321(p)(1) and/or 21 U.S.C. § 321(p)(2);

d. Whether the Defendants' purported practices involve "biological products" within the meaning of the Public Health Service Act ("PHSA"), 42 U.S.C. § 262(i);

e. Whether the Defendants' purported practices involve "human cells, tissues, or cellular or tissue-based products" ("HCT/Ps"), defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d);

f. Whether the Defendants' CSCTC products/SVF procedures qualify for the "same surgical procedure exception" in 21 C.F.R. § 1271.15(b);

g. Whether the Defendants' CSCTC products/SVF procedures meet all of the criteria in 21 C.F.R. § 1271.10(a) for regulation solely under the PHSA and 21 C.F.R. Part 1271;

h. Whether the FDA lacks jurisdiction under the FDCA, the U.S. Constitution, or otherwise to regulate Defendants' CSCTC products/SVF procedures.

i. Whether the Defendants' purported practices use methods, facilities, and controls that conform to CGMP. *See* 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-211; *see also* 21 C.F.R. Parts 600-680 (setting forth additional standards and manufacturing requirements applicable to biological products);

j. Whether the Defendants' CSCTC products, as alleged in the Complaint, are adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(B), or misbranded within the meaning of the FDCA, 21 U.S.C. § 352(f)(1) or 353(b)(4);

k. Whether the Defendants' SVF/Vaccinia product, as alleged in the Complaint, is misbranded within the meaning of the FDCA, 21 U.S.C. § 352(j);

l. Whether Defendants violate 21 U.S.C. § 331(k) by causing the adulteration of CSCTC products within the meaning of 21 U.S.C. § 351(a)(2)(B);

m. Whether Defendants violate 21 U.S.C. § 331(k) by causing the misbranding of CSCTC products within the meaning of 21 U.S.C. § 352(f)(1), 352(j), and 353(b)(4); and

n. Whether Defendants violate 21 U.S.C. § 331(c) by receiving in interstate commerce and delivering or proffering for delivery drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) and 353(b)(4);

D. Parties, Evidence, etc.

Parties

Plaintiff – United States

Defendants – CSCTC, CSN, Lander, and Berman

Plaintiff's Evidence

In addition to the witnesses and documents identified by the Defendants, the United States identifies the following witnesses and documents. Additional witnesses and documents may come to light upon discovery and the United States reserves the right to make revisions.

Witnesses

1. Karlton Watson, Program Division Director
2. Catherine Quinlan, Director of Compliance Branch
3. Sam Labinjo, Compliance Officer

4. Daniel Cline, Compliance Officer
5. Randall Morris, Compliance Officer
6. William Frederick Lagud, Jr., Consumer Safety Officer
7. Cynthia Jim, Consumer Safety Officer
8. Darla J. Christopher, Consumer Safety Officer
9. Michele L. Forster, Consumer Safety Officer
10. Kip Hanks, Consumer Safety Officer
11. Cody Rickman, Consumer Safety Officer
12. Christopher C. Joneckis, PhD, Associate Director for Review Management
13. Shawntae Dowell, Surgical Technologist
14. Brittany White, Surgical Technologist
15. Judi E. Meglio, Office Manager
16. Audrey Fianza, Certified Scrub/Surgical Technologist

Key Documents

1. Inspectional Observations ("Forms FDA 483")
2. Establishment Inspection Reports ("EIRs")
3. FDA Sample Collection Reports
4. Consumer Complaints
5. Published Articles
6. Files downloaded from the internet
7. Correspondence between FDA and Defendants

Defendants' Evidence

In addition to the witnesses and documents identified by the United States, Defendants identify the following additional witnesses and documents in this action. Additional witnesses and documents may come to light upon discovery and Defendants reserve the right to make revisions.

Witnesses

1. Defendant Berman

2. Defendant Lander
3. Sean Berman
4. CSCTC and CSN patients

Key Documents

1. FDA statements regarding the pertinent regulatory scheme, including the Same Surgical Procedure Exemption
2. Communications between FDA and Defendants
3. Non-privileged internal FDA communications about Defendants
4. Non-privileged internal FDA communications about SVF procedures
5. Scientific articles regarding the Defendants' SVF procedures
6. Documents describing the Defendants' SVF procedures

E. Damages

Not applicable.

F. Insurance

Not applicable.

G. Motions

The Parties do not anticipate filing any motions to add parties or claims, amend the pleadings, or transfer venue at this time, but may seek leave to do so depending on the results of discovery.

H. Manual for Complex Litigation

The Parties agree that this is not a matter requiring the Manual for Complex Litigation.

I. Status of Discovery

The Parties have satisfied their meet and confer obligations under Federal Rule of Civil Procedure 26(f), Local Rule 26-1, and this Court's July 18, 2018 Order Setting Scheduling Conference.

The Parties will exchange their Rule 26(a) Initial Disclosures on September 24, 2018. Due to the breadth and scope of this case, both Parties reasonably expect that

supplemental disclosures may have to be made pursuant to Federal Rule of Civil Procedure 26(e).

The Parties intend to propound requests for admission and interrogatories on the topics outlined in section C above, with responses due within thirty (30) days of service.

Additionally, the Parties continue to work towards a set of facts that can be stipulated to without discovery.

J. Discovery Plan

Proposed Changes to Rule 26(a) Disclosures

The Parties agree that no changes to the disclosures under Federal Rule of Civil Procedure 26(a) are necessary. The Parties will exchange initial disclosures on September 24, 2018, and have agreed, consistent with their obligations under Federal Rule of Civil Procedure 26(e), to amend their disclosures as new information becomes available.

Discovery

Because the disputed matters in this case involve largely legal issues, the Parties agree that discovery should be conducted in phases in accordance with the schedule set forth below.

The Parties propose that the first phase of discovery will consist of the United States disclosing to Defendants documents and records related to FDA's inspections of Defendants' facilities that occurred between June 17 and June 27, 2017, as well as a round of interrogatories and requests for admission from each Party to the extent necessary to address material facts in dispute. Among other things, the Parties intend to propound interrogatories and requests for admission relating to the allegations in FDA's Complaint, Defendants' affirmative defenses, and the topics outlined in Section C above. The Parties believe that a limited phase of discovery should likely enable the Parties to fully brief dispositive motions for summary judgment framing the contested legal issues for the Court, while at the same time conserving the Parties' resources by not taking or defending depositions or responding to requests for production unnecessarily.

Out of an abundance of caution, however, the Parties propose an additional phase of discovery involving depositions and requests for production, to the extent such is even necessary to address genuine issues of fact remaining after the initial phase of discovery is completed. The chart below outlines the Parties' discovery plan and what discovery they intend to conduct at each phase of the discovery process:

DEADLINE OR EVENT	AGREED DATE
Phase 1 Discovery Begins (all claims and defenses) • Requests for Admissions • Interrogatories	September 14, 2018 (first day Requests for Admission and Interrogatories may be served)
Production to Defendants of documents and records related to FDA's inspection of Defendants' facilities that occurred between June 17 - 27, 2017	September 24, 2018
Last Date to Amend Pleadings or Add Parties without leave of Court	November 15, 2018
Deadline for completion of all Phase 1 discovery	December 17, 2018
Phase 2 Discovery Begins (remaining issues of material fact) • Depositions (as needed) • Requests for Production (as needed)	December 17, 2018 (first day Requests for Production and Deposition Notices may be served)
Disclosure of Expert Report(s) – initial	January 7, 2019
Disclosure of Expert Report(s) – rebuttal	February 6, 2019
Deadline for completion of all Phase 2 discovery (including hearing all discovery motions)	March 31, 2019

Last date to conduct settlement conference	April 30, 2019
Deadline to file all motions, including judgment motions, motions related to summary judgment, and *Daubert* motions	May 31, 2019
Deadline to argue/hear all non-discovery motions	June 24, 2019
Deadline to file all other trial-related motions, including motions *in limine* directed towards trial evidence	July 8, 2019
Deadline to file Memorandum of Contentions of Fact and Law; Witness Lists; Joint Exhibit List; and Oppositions to motions in limine	July 15, 2019
Deadline to file Proposed final pretrial conference order; Proposed jury instructions, and any objections; Proposed verdict forms; and Statement of the case	July 22, 2019

Electronically Stored Information

The Parties do not expect that there will be significant electronically stored information ("ESI") relevant to the claims and defenses in this case. The Parties have engaged in discussions to develop a plan that is proportional and reasonable in relation to the nature of the complexity of the case, for the preservation, identification and production of the relevant ESI. See Parties' Joint Plan for Discovery of Electronically Stored Information, attached as Exhibit B.

Claims of Privilege

In the event that discovery should need to proceed beyond the first phase of discovery, the United States anticipates filing a protective order shielding from discovery any agency documents or communications that are covered by any applicable privilege, including the deliberative process or law enforcement investigatory privileges. The Parties will confer in a good-faith effort to reach an agreed-upon protective order, which the Defendants reserve the right to contest.

The Parties agree to use the procedures set forth in Federal Rule of Civil Procedure 26(b)(5) to resolve any disputes regarding claims of privilege or protecting materials asserted as being for trial-preparation. The parties request that this proposed procedure be adopted within the Court's further orders.

K. Discovery Cut-off

See Schedule of Pretrial and Trial Dates, attached as Exhibit A.

L. Expert Discovery

See Exhibit A.

M. Dispositive Motions

Following sufficient discovery, the Parties expect to file motions for summary judgment or adjudication on some or all of their claims, as well as any motions *in limine* dictated by discovery. In particular, the Parties anticipate moving for summary judgment or partial summary judgement, in part, on the threshold legal question of whether FDA has authority under the FDCA and the Constitution to regulate Defendants' CSCTC products/SVF procedures.

N. Settlement/Alternative Dispute Resolution

The Parties have discussed settlement at length, including during in-person meetings attended by counsel for the Parties and for FDA on April 27, 2018, and on May 8, 2018. Despite the Parties' good-faith attempts at settlement, a negotiated resolution does not appear likely prior to the Court's resolution of the threshold legal issues concerning the applicability of the FDCA to the Defendants' CSCTC products/SVF procedures. Thereafter, the Parties agree to utilize the Court Mediation Panel.

O. Trial Estimate

The Parties do not request a jury trial. The Parties expect the trial to take 5-7 days. At this time, the United States contemplates calling 15 witnesses, and Defendants anticipate calling 15 witnesses. The Parties reserve the right to call additional witnesses.

P. Trial Counsel

Trial counsel will include Natalie Sanders for the United States and Celeste Brecht and Witt Chang of Venable LLP for the Defendants.

Q. Independent Expert or Master

At this time, the Parties agree that there is no need for an independent scientific expert or for a master pursuant to Rule 53, but the Parties respectfully request that a reference be available should a need arise.

R. Timetable

See Exhibit A.

S. Other Issues

As noted above, the Parties anticipate that limited discovery will enable the Parties to brief dispositive motions for summary judgment framing the threshold legal issues for the Court. In the event that discovery should need to proceed beyond the first phase of discovery, the United States on behalf of FDA anticipates filing a protective order for any depositions of FDA personnel not involved in the inspections of Defendants' facilities leading to the instant cause of action. The Parties will confer in a good-faith effort to determine whether such a protective order is necessary. Defendants expressly reserve all rights to contest the need or scope of such a protective order, and expressly reserve all rights to notice the deposition of any witness who may possess relevant knowledge. Similarly, the United States on behalf of the FDA would anticipate filing a protective order shielding from discovery any agency documents or communications that are covered by any applicable privilege, including the deliberative process or law enforcement investigatory privileges. The Parties will confer in a good-faith effort to determine whether such a protective order is necessary. Defendants expressly reserve all rights to contest the need or scope of such a protective order, and expressly reserve all rights to seek and compel the production of all relevant documents and communications.

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CALIFORNIA STELL CELL TREATMENT CENTER, INC., et al.

All signatories listed on whose behalf this filing is submitted concur in the filing's content and have authorized the filing (L.R. 5-4.3.4(a)(2)(i)).

Exhibit A: Schedule of Pretrial and Trial Dates Worksheet

Exhibit B: Joint Plan for Discovery of Electronically Stored Information

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of September 2018, I electronically filed a true and correct copy of the foregoing JOINT RULE 26(F) REPORT through the Court's CM/ECF system, which will send a notice of electronic filing to the following:

Celeste M. Brecht
Witt W. Chang
VENABLE LLP

/s/ Natalie N. Sanders
NATALIE N. SANDERS